REMARKS

Claims 1, 3, 4, 7-10, 12, 13 and 16-19 are in this application and are presented for consideration. By this Amendment, Applicant has amended claims 1, 3, 4, 7, 8, 9, 10, 12 and 16. Applicant has also added new claim 19. Claims 2, 5, 6, 11, 14 and 15 have been canceled.

Claims 1 and 10 have been rejected under 35 U.S.C. 102(b) as being anticipated by Burke (US 4,803,994).

The present invention relates to an ultrasonic diagnostic device and an ultrasonic diagnostic method. Conventional ultrasonic diagnostic methods for heart disease are based on morphological aspects of the heart. However, these conventional techniques are not helpful in the tissue characterization of cardiac muscle. A problem exists in that in order to characterize the tissue of the heart, a biopsy of the cardiac muscle is required. This is an invasive technique and imposes a heavy physical and mental burden on the patient and cannot be repetitively applied. The present invention solves this problem by providing a noninvasive tissue characterization method and device that is applicable to cardiac muscle.

Applicant has measured ultrasonic integrated backscatter from the heart wall of a healthy patient at a repeated transmission frequency of a few kHz. The ultrasonic integrated backscatter is measured as an average reflective power of ultrasound from a given region in the heart wall. The intensity of the integrated backscatter from the heart wall is known to manifest cyclic variations matching the pulsation of the heart. While measuring the ultrasonic integrated backscatter in the healthy patient, Applicant discovered a component varying at a frequency of

tens to hundreds of Hz superimposed over the cyclic variations in addition to the already known cyclic variations. The present invention was produced based on this discovery. The present invention advantageously obtains the average power of the integrated backscatter from the region of interest by measuring the ultrasonic integrated backscatter at a high repeated transmission frequency of a few kHz. This variation frequency or variable cycle is then supplied to a monitor for display. This advantageously provides an ultrasonic diagnostic system that acquires detailed information on local tissue characteristics of cardiac muscle by utilizing ultrasonic backscatter. This advantageously allows a more accurate diagnosis of heart disease. The prior art as a whole fails to teach such features or advantages.

Burke discloses a backscatter data collection technique for ultrasound. A transducer 10 comprises a plurality of transducer elements in an array. The transducer 10 is coupled to a front-end processor 11 which includes a pulser 12 and a demodulator and signal processor 13. The ultrasound system includes a mid-processor 15, display processor 16 and a display 17. Pulser 12 energizes transducer array 10 to insonify along a vector angle in an object. In a receive mode, signals detected by transducer array 10 are coupled to demodulator and signal processor 13 which operates to provide a summed in-phase signal I and summed quadrature signal Q. Mid-processor 15 determines the backscatter intensity based on signals I and Q. The intensity or other backscatter feature is provided to a display processor 16 for presentation on display 17. Narrowband interrogating frequencies are used to maximize signal-to-noise ratio and to minimize location errors.

Burke fails to teach and fails to suggest the combination of measuring a backscatter

intensity from a heart wall by using a frequency of a few kHz. At most, Burke discloses using a few MHZ frequency. With such a frequency, it is impossible to measure the component that varies at a frequency of tens to hundreds of Hz in the ultrasonic backscatter in the heart wall as featured in the claimed combination. Applicant has discovered a new component that varies at a frequency of tens to hundreds of Hz superimposed over the cyclic variation based on the backscatter at a heart wall. This new component was discovered when using a frequency of a few kHz. In the present invention, the ultrasonic backscatter from the heart wall can be measured at a frequency of a few kHz in order to obtain this variation frequency. This advantageously provides for more accurate details on the local tissue characteristics of cardiac muscle so that heart disease can be more accurately detected. Burke fails to appreciate measuring this new component that varies at a frequency of tens to hundreds of Hz in the ultrasonic backscatter in the heart wall. Further, Burke cannot measure such a component since Burke does not disclose applying a frequency of a few kHz. In contrast to the present invention, Burke merely discloses applying ultrasonic bursts at 2.5 MHZ and 3.6 MHZ. As such, Burke takes a different approach and fails to teach or suggest the features as claimed. Accordingly, Applicant respectfully requests that the Examiner favorably consider claims 1 and 10 as now presented and all claims that depend thereon.

Claims 2 and 11 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Burke in view of Papadofrangakis et al. (US 4,217,909).

As previously discussed above, Burke fails to teach or suggest measuring a backscatter intensity from a heart wall by using a frequency of a few kHz. By measuring a backscatter

intensity across a selected volume of tissue using the MHZ frequencies of 2.5 and 3.6 as disclosed in Burke, it is impossible to measure the component that varies at a frequency of tens to hundreds of Hz in the ultrasonic backscatter in the heart wall as claimed. Further, Papadofrangakis et al. fails to teach or suggest measuring ultrasonic backscatter from a heart wall at a frequency of a few kHz in order to obtain a variation frequency, which is a frequency of tens to hundreds of Hz. At most, Papadofrangakis et al. discloses measuring Doppler frequency shifts in blood flow by using an audio spectrum of 0.2 - 8 KHz. Papadofrangakis et al. fails to provide any suggestion of using the 0.2 - 8 kHz to measure the ultrasonic backscatter in a heart wall. Measuring the characteristics of blood flow are very different from measuring the backscatter in a heart wall to determine the local tissue characteristics of cardiac muscle. As such, Papadofrangakis et al. fails to provide any teaching of using the disclosed frequencies to measure ultrasonic backscatter in a heart wall. Accordingly, Applicant respectfully requests that the Examiner favorably consider claims 1 and 10 and all claims that depend thereon.

Claims 3-5, 7-9, 12-14 and 16-18 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Burke in view of Kanai et al. ("Real-time Measurements of Local Myocardium Motion and Arterial Wall Thickening", September 1999).

Although Kanai et al. teaches a method for real-time measurements of local myocardium motion and arterial wall thickening, the references as a whole fail to suggest the combination of features claimed. Specifically, Burke provides no teaching for the combination of using a frequency of a few kHz to measure a component which varies at a frequency of tens to hundreds of Hz in the ultrasonic backscatter in the heart wall. The references together do not

suggest the combination of features claimed. One of ordinary skill in the art is presented with various concepts, but these concepts do not provide any direction as to combining the features claimed. All claims define over the prior art as a whole.

Claims 6 and 15 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Burke in view of Kanai et al., and further in view of Kanai et al. 1997 ("Noninvasive Evaluation of Local Myocardial Thickening and Its Color-coded Imaging", July 1997).

Although Kanai et al. 1997 teaches a method for evaluating local myocardial thickening, the references as a whole fail to suggest the combination of features claimed. Specifically, Burke provides no suggestion for the combination of using a frequency of a few kHz to measure a backscatter intensity at a heart wall. The references together do not suggest the combination of features claimed. One of ordinary skill in the art is presented with various concepts, but these concepts do not provide any direction as to combining the features claimed. All claims define over the prior art as a whole.

Applicant has added new independent claim 19. New claim 19 provides for similar features as found in method claim 10, but in different claim language. Claim 19 further provides for the display means to display the diagnostic data in a viewable format. Applicant respectfully requests that the Examiner favorably consider new claim 19 as presented.

Favorable action on the merits is requested.

Respectfully submitted
for Applicant,

By:_____
John James McGlew
Registration No. 31,903
McGLEW AND TUTTLE, P.C.

JJM:BMD
71532-7
Attached: Petition for One Month Extension of Time

DATED: July 6, 2007
BOX 9227 SCARBOROUGH STATION
SCARBOROUGH, NEW YORK 10510-9227
(914) 941-5600

SHOULD ANY OTHER FEE BE REQUIRED, THE PATENT AND TRADEMARK OFFICE IS HEREBY REQUESTED TO CHARGE SUCH FEE TO OUR DEPOSIT ACCOUNT 13-0410.